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510(k) Summary

APR 12 2011

Submitted by: Coreleader Biotech Co., Ltd.
19F, No. 100, Sec. 1, Sintai 5th Rd., Sijhih, Taipei, Taiwan, 22102
Phone: +886-2-26968880
FAX: +886-2-26968882

Contact Person: Teeming Tsao

Date Prepared: September 20, 2010

Proprietary Name: Coreleader Algi-Fiber Wound Dressing

Common Name: Topical Wound Dressing

Classification: Unclassified

Classification Name: Hydrophilic Wound and Burn Dressing

Predicate Device: CALGON VESTAL DIV., K910059, KALTOSTAT WOUND DRESSING
COLOPLAST CORP., K983519, COMFEEL SEASORB DRESSING

	COMFEEL SEASORB DRESSING	CORELEADER ALGI-FIBER WOUND DRESSING
Device description	The Comfeel SeaSorb Dressing is a highly absorbent material composed of a Xerogel of calcium sodium alginate cast into a high density polyethylene net.	The Coreleader Algi-Fiber is a highly absorbent wound dressing consisting of an calcium alginate fiber.
Use(single, reusable)	Single	Single

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	COMFEEL SEASORB DRESSING	CORELEADER ALGI-FIBER WOUND DRESSING
Bio-compatibility	Non-hypersensitivity、non-cytotoxicity and non-irritant	Non-hypersensitivity、non-cytotoxicity and non-irritant
Intended use	For management of (under the guidance of a health care professional) moderate to heavily exudating wounds, including leg ulcers and pressure sores, etc.	For management of (under the guidance of a health care professional) moderate to heavily exudating wounds, including leg ulcers and pressure sores, etc.
Precautions	Wounds which are solely or mainly caused by arterial insufficiency or complicated diabetic wounds (primarily lower leg and foot) should be inspected by a physician or nurse regularly. A physician should be consulted before using this product on wound with a high risk of infection, or on lesions caused by syphilis, tuberculosis, leprosy or cancer. Comfeel Seasorb dressing must be removed prior to the following treatments: radiation, X-rays,	Coreleader Algi-Fiber Wound Dressing should not be used on individuals who are sensitive to or who had an allergic reaction to the dressing or its component. Algi-Fiber must not be used as a surgical implant. The Wound Dressing may be used on high risk of infected wounds only under the care of clinical physicians. The dressing can't be left in the wound permanently and should be inspected by a physician or nurse regularly. Wounds with signs of

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	ultrasonic treatment, diathermy and micro waves. Wounds with signs of clinical infection, fever and local symptoms such as pain, erythema or pus should have a bacterial swab examination. Use of this product may be continued at the discretion of a physician. Current systemic antibiotic treatment may be give if indicated. Not recommended for use on dry wounds or third degree burns. Do not use on patients with known hypersensitivity to any of the ingredients.	clinical infection, fever and local symptoms such as pain, erythema or pus should have a bacterial swab examination. Use of this product may be continued at the discretion of a physician. Current systemic antibiotic treatment may be give if indicated. The product is for single use only and should not be re-sterile. Reuse or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection. Not recommended for use on dry wounds or third degree burns.
Sterilization	Sterile	Sterile
Packaging	Polyester pouches laminated with peelable polyethylene prior to sterilization	Sterilization pouch: Top material: Medical grade paper pouches. Bottom material: Transparent see-through film (made of PET).

Device Description: Coreleader Algi-Fiber wound dressing is composed of calcium alginate fiber. It is softness and therefore Coreleader Algi-Fiber wound dressing is suitable for wound surface regardless the

location, size, sinus and depth of a patient. Due to its highly hydrophilic property, the Coreleader Algi-Fiber wound dressing absorbs the wound exudates to form a hydrogel protection layer.
The Coreleader Algi-Fiber wound dressing is biocompatibility. It has been tested and shown on accumulative effects, no evidence of delay hypersensitivity · non-cytotoxicity and is non-irritant.
Coreleader Algi-Fiber is a sterile topical wound dressing, packed in individual pouch and sterilized by r-ray radiation to a 10^{-6} SAL.

Intended Use: Coreleader Algi-Fiber wound dressing is indicated as a primary dressing for the management of moderate to heavily exuding wounds, partial and full thickness wounds including chronic wounds such as leg ulcers, pressure sores and acute wounds such as donor sites, abrasions, lacerations and post-surgical wounds.

Technological Characteristics: Coreleader Algi-Fiber wound dressing is manufactured by a Wet-Spinning production process. Made of non-woven from calcium alginate fiber. The dressing is presented as a dense, flat non-woven pad for application to surface wounds. In the presence of exudate or other body fluids containing sodium ions, the fibers absorb liquid and swell and calcium ions present in the fibers are partially replaced by sodium ions, causing the dressing to take on a gel-like appearance. This overlays the wound and provides a micro-environment that is believed to facilitate wound healing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Coreleader Biotech Co., Ltd.
% Mr. Ian Li
19F, No. 100, Sec. 1,
Sintai 5th Rd, Sijhih,
Taipei, Taiwan 22102

APR 12 2011

Re: K102943
Trade/Device Name: Coreleader Algi-Fiber Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 11, 2011
Received: February 18, 2011

Dear Mr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102943

Device Name: Coreleader Algi-Fiber Wound Dressing

Indications for Use:

The following indications for use of the product should be managed under the supervision of a health care professional:

Coreleader Algi-Fiber wound dressing is indicated as a primary dressing for the management of moderate to heavily exuding wounds, partial and full thickness wounds including chronic wounds such as leg ulcers, pressure sores and acute wounds such as donor sites, abrasions, lacerations and post-surgical wounds.

The following conditions are considered appropriate for OTC use by the lay person:

Coreleader Algi-Fiber wound dressing is indicated as a primary dressing for the management of minor exuding wounds such as minor abrasions, minor lacerations and minor post-surgical wounds.

Prescription Use _V__ AND/OR Over-The-Counter Use _V__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krmpotic MXM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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